Commentary: reliable data are not yet available

Epilepsy is a syndrome of varying aetiology. Although drugs do not seem to be effective in head injured patients, the natural course of epilepsy in these patients seems unlikely to be the same as that in a person with no identifiable cause. The preliminary data on treatment after a first seizure are encouraging but far from definitive, and it is in this area that most effort must be concentrated. The social implications of diagnosing epilepsy after the first seizure are substantial, making it all the more important that reliable data are obtained. Though the widespread use of anticonvulsant drugs prevents a comprehensive study on the natural course of epilepsy in all its forms, the effect of treating or not treating the first seizure should be thoroughly investigated.—PETER C RUBIN, *professor of therapeutics, University of Nottingham*

difficult to encourage patient compliance after one or two seizures than after a clear pattern of epilepsy has been established. Treating epilepsy before the first seizure presents even more difficulties.

Conclusion

The decision to start antiepileptic drugs is difficult for any patient. Currently, we are unable to offer patients enough information to make this decision easy or to encourage compliance with early treatment. The estimates of risks of a second seizure after the first vary widely,[11] and even less information is available about the risk of third seizures after a second. We need studies that allow a precise estimate of the differences in short term recurrence of seizures with and without treatment as well as an estimate of how different the chance of long term cure (remission without antiepileptic drug treatment) is if treatment is started early rather than later. These estimates would need to be set against information about the risks of adverse effects of the treatment. This information should allow patients to make more fully informed decisions about when they wish to start treatment.

Any doctors interested in collaborating in an MRC sponsored randomised study of early and deferred treatment in patients with single seizures or early epilepsy should contact me.

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The World Health Organisation

WHO's special programmes: undermining from above

Fiona Godlee

This is the sixth in a series examining the role of the World Health Organisation, its current problems, and its future prospects.

British Medical Journal, London WC1H 9JR
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BMJ 1995;310:178-82

Despite the World Health Organisation's spoken commitment to developing integrated primary health care, its most visible and successful activities are not integrated within countries; they are its disease specific intervention programmes, such as the Global Programme on AIDS and the programmes for the control of diarrhoeal and acute respiratory diseases. The 10 or so special programmes, all but one of which (the onchocerciasis control programme) are based in Geneva, have found increasing favour among donors, but critics say that they undermine WHO's attempts to integrate its activities at country level and discourage countries from developing their own capacity.

WHO's special programmes were set up in response to the perceived need among donors for something more comprehensive than WHO's regional and country based activities could offer. The idea is that they boost the organisation's routine activities, using international and regional expertise and a project based approach to attack specific diseases or health issues. The special programmes receive no funds from WHO's regular budget. They are funded from so called extrabudgetary contributions. Because of this they are not under the control of the director general, the executive board, or the World Health Assembly. Each special programme has its own director and a management executive committee made up of donors' representatives.

From the donors' point of view the special programmes have clear advantages over WHO's non-project based activities. They have well defined aims and strategies; they have outcome measures, even if most relate to process rather than health indicators; they are more financially accountable than the rest of WHO; and they are not under the direct control of the secretariat. This last point has become increasingly important in the past five years, according to diplomats in Geneva. As donors in Europe, Scandinavia, and America have become increasingly discontented with the organisation's lack of leadership and accountability they have concentrated their funding of WHO more and more in extrabudgetary donations. Extrabudgetary payments to special programmes now make up over half of the organisation's total income, compared with a quarter in 1972.

The shift to extrabudgetary funding restores to donor countries much of the influence they lost during the 1970s, when the influx into WHO of countries from the developing world more than doubled its membership. All countries have equal voting rights at the

World Health Assembly, so groupings of countries from the developing world can now control the assembly's agenda. By shifting their funds to the special programmes, donors can influence how their money is spent. A spokesman for one European aid organisation said, "We invest in these programmes because we have control over what we invest in. If we don't like what happens we can vote with our cheque book." The arrangement has advantages for recipient countries too. The regular budget has been frozen in real terms for the past 13 years, which means that membership payments are falling against inflation, but extrabudgetary funds keep the money coming in.

The problems of donor power

The change is not without its problems for WHO. Instead of working in a coordinated way towards a set of centrally agreed goals, the organisation has become an umbrella within which its independent programmes compete for funds. According to international aid workers, this reduces WHO's impact and can create confusion and bad feeling. Recipient countries complain of lack of coordination between different parts of the organisation.

"Having two types of funding is an important structural weakness," said a staff member in Geneva. "Programmes are forced to go begging for money, and they have to compete with each other, which is absurd. Donors feel more comfortable with this arrangement, more in control. But because the World Health Assembly doesn't discuss the extrabudgetary programmes, the multilateral system for setting priorities is effectively bypassed." Priorities depend on the energy with which each programme lobbies for support, explained another staff member. Such efforts may be motivated in part by the desire among specialists on each programme to keep and strengthen their own positions. "These specialists need the jobs," he said.

WHO's priorities increasingly reflect those of the major donor nations. As Dr Jonathan Mann, former director of the global programme on AIDS and now director for the International Centre for AIDS at Harvard, puts it, "The tail is now wagging the dog." The United States, for example, puts three fifths of its £100m extrabudgetary contributions into the global programme on AIDS, which is now WHO's largest single programme and one of the largest in the United Nations. Meanwhile, until recently the United States refused to donate money to maternal and child health programmes that might advocate abortion.

Dr Gill Walt of the London School of Hygiene and Tropical Medicine identifies other problems of "donor power."[1] Big donors can and do use the threat of withdrawing funds to exert political pressure. Threats by the United States to withdraw from WHO kept the Palestine Liberation Organisation from attaining full membership until last year. Also, donor governments are answerable to their own voters and need to see results. This tends to encourage them to invest in short term, technically driven programmes and to judge them by short term outputs (such as the number of immunisations given) rather than long term outcomes (such as reductions in mortality or improved quality of life).

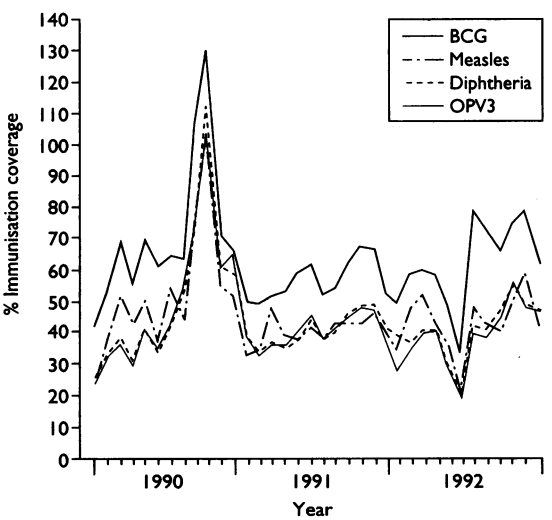
"Extrabudgetary contributions allow donors to escape from their responsibilities," said one member of WHO's staff. "They can go for glamorous diseases like AIDS, which grab the attention of the voting public, but they are not so interested in, say, polio, which is remote and gives results only in the much longer term." Finally, the shift towards extrabudgetary donations means that more time at meetings between donor nations and WHO is now spent debating financial discipline and budgets rather than defining and formulating policy.[2]

A recent paper from the Karolinska Institute in Sweden points out another quirk of the funding of special programmes.[2] Much of the money donated for research finds its way back to the donor country. From 1975-89, America gave $33m to the tropical diseases research programme. Over the same period it received $44·4m from the programme in research grants. Meanwhile Britain received back over a third of its $43·3m donation to the programme for research on human reproduction from 1972-92. The authors of the paper conclude that "the cost effectiveness of transferring large sums of national money through WHO and back to the country of origin must be questioned."

Need for integration

The special programmes look set to remain a major part of WHO's activities, and WHO is aware of the need to integrate them into local health care systems if they are to be sustainable. "Horizontal integration is the main tool for survival of the programmes," said Dr Anton Fric, medical officer to the expanded programme on immunisation in South East Asia. "It is especially important if donor funds begin to decline." He believes that the immunisation programme is now well integrated at central and district level in most countries in the region and that other programmes will now be able to use the programme's networks to spread advice on AIDS and maternal and child health.

The immunisation programme has, however, run into problems, largely because WHO depends on Unicef for its implementation. WHO's initial plan recognised that setting up a vaccination programme would not only be a valuable intervention in itself but would also provide vital experience in developing health care systems across the board. But according to international aid workers, the original principles were lost with Unicef's decision to work towards the quantitative goal of universal childhood immunisation by 1990. Instead of gradually developing health care infrastructure, as envisaged by the first director of WHO's immunisation programme, Dr Rafe Henderson, Unicef injected vast sums of money and external manpower in an attempt to satisfy its donors with visible results. As 1990 approached and countries in Africa continued to lag behind even the rescheduled target of 80% vaccine coverage, Unicef poured in resources for mass vaccination campaigns. Data from Ghana show the result: a massive surge in coverage in 1989-90, allowing Unicef to claim success, but an



Immunisation coverage in Ghana[3]—an example showing that, without additional funds for mass vaccination campaigns (1990), levels are usually 40-50%

almost immediate return to levels of 40-50% when the additional resources were removed (see figure). According to Unicef, coverage in Nigeria has followed the same pattern, peaking at 70% in 1990 and falling to under 20% in 1994.

Harsh lessons unlearnt

The problems besetting the immunisation programme illustrate the pitfalls of single strategy, top down interventions. Large sections of WHO, and the special programmes in particular, remain wedded to this approach. Since eradicating smallpox in 1978, and with the millenium approaching, WHO is understandably keen to do the same with the other major tropical diseases. The success with smallpox may not, however, be repeatable. Experts attributed its eradication largely to clear strategic planning but also to specific characteristics of the disease. Smallpox has no animal reservoir and no subclinical or carrier state. Its clinical manifestations are clearly recognisable. This meant that cases could be identified by lay people such as village chiefs, and WHO's staff did not have to screen individuals. Case monitoring could be done over large areas.

For different reasons, the eradication of polio looks increasingly achievable. The vaccine virus is secondarily transmitted, especially in endemic areas where there is poor sanitation. As a result of this multiplication effect, coverage of whole areas can be achieved without attempting comprehensive individual coverage.

ERADICATING MALARIA

Other diseases are proving less amenable to eradication, and in one famous case, malaria, intervention has left large areas of the world far worse off than before. The current malaria pandemic is, says Dr Andrew Spielman of the department of tropical public health at Harvard, an iatrogenic phenomenon.[4] WHO's malaria control programme was set up in 1956. In 1958 the American government announced its plans for an "intensified effort" against the disease, and unlike WHO's open ended commitment, the Congress specified a five year time limit. The plan, based on the ideas of Professor Paul Russell of Harvard University, was to eradicate the disease within the limited three to five year window of opportunity before resistance to drugs and pesticides set in. Vast sums were invested in spraying houses with pesticides, the money coming largely from USAID, America's overseas aid organisation.

The initial success was extraordinary. In Sri Lanka, the annual incidence fell from 1 million in a population of 12 million exposed people in the early 1950s to 18 cases in 1963. Eradication, at least in some areas of the world, seemed guaranteed. But the plan had been based on the premise that populations were homogeneous and that those who escaped the spraying programme—itinerant workers, for example—would be equally spread throughout an area. Professor Russell estimated that covering 80% of houses would be sufficient. He did not take into account the possibility of clusters of migrant workers—gem miners in Sri Lanka, for example—who served as an unreachable reservoir for the parasite. By 1963, the year that USAID was due to pull out of the scheme, resistance to DDT had arrived, soon to be followed by resistance to the main antimalarial drugs, and the battle against malaria was lost. WHO was left to pick up the pieces.

WHO's response over the past 20 years has been to retreat into research. Its tropical diseases research programme, which spends a fifth of its budget on malaria, has had notable successes. Almost all of the new drugs for treating malaria have come out of research collaborations funded by WHO, and the programme is now testing drugs and vaccines for effectiveness and toxicity. Dr Diane Worth, an expert in tropical diseases at Harvard University, sees this

What makes a good special programme

The programme for control of diarrhoeal diseases is generally viewed as one of WHO's most effective special programmes. A recent external review concluded that it was "well managed with high standards of performance, strong leadership, high staff quality, and a focus on strengthening country programmes."[5]

The programme is important in global terms: according to the World Development Report 1993, diarrhoeal diseases account for a sixth of the total disease burden in children under 5. By the end of 1991, as a result of WHO's initiatives, diarrhoeal disease programmes had been set up in 129 countries, covering 99% of the population of the developing world, and 92 countries had undertaken reviews of their programmes. Most countries had nearly reached the 1995 target of providing 80% of the population with a regular supply of oral rehydration salts, and the programme is working to encourage countries to produce their own supplies. It has succeeded in curtailing inappropriate drug treatment of diarrhoea; many countries, including the Phillipines, Pakistan, and Zambia, have removed inappropriate drugs from their national formularies. The substantial fall in mortality from diarrhoeal disease in most parts of the developing world over the past 15 years is a positive sign,[4] although how much can be attributed to WHO remains uncertain.

Dr Jim Tulloch, the programme's director, attributes its success to several factors. One is that it has both research and implementation arms: "This means that the research we do is highly relevant to programme implementation and that, in return, development can immediately make use of research findings." By contrast, WHO's tropical diseases research programme does only research. Its counterpart from implementation is the tropical diseases control programme, which is in a different division of WHO. "It is difficult enough getting programmes to work together when they are in the same division," said Dr Tulloch.

Another reason for success, says Dr Tulloch, is the programme's strong emphasis on prevention. After assessing the cost effectiveness of different preventive strategies, he and his team decided to concentrate on promoting breast feeding, and the programme now employs two full time staff working on this in Geneva.

In the past the programme for control of diarrhoeal diseases has been criticised, like others, for being insufficiently integrated within countries. Dr Tulloch says that this is being rectified. His division in Geneva now also includes the programme for control of acute respiratory diseases, with a joint budget allocation of $33m for 1994-5, and he has been able to establish links between the two programmes at all levels. WHO has several special programmes promoting integration of health care within its member states—dealing with, for example, the development of health infrastructure and primary care—but their approach is largely theoretical. Dr Tulloch prefers a more practical approach. Eighteen months ago he launched the sick child initiative. Ten units within WHO are now collaborating to tackle diarrhoea, acute respiratory infection, measles, malaria, and malnutrition, which together account for 70% of all deaths in children under 5.

Strong and effective leadership is an important ingredient in the programmes' success. Between them the diarrhoeal and respiratory diseases programmes have build up a reputation for integrity and for focusing on the issues rather than internal politics and personalities. "They have taken a firm line over a long period, and everyone knows that it's not easy to force on them policies or people they don't want," said one member of staff. "As a result they don't get mixed up in all the political hassle."

Out of Geneva

Many feel that WHO's special programmes are obvious candidates for removal from the expensive and, in terms of tropical disease, irrelevant setting of Geneva. Supporters of this view refer to a programme that has become one of Africa's rare success stories. The onchocerciasis control programme has already achieved its 1995 objective of eliminating the disease as a public health or socioeconomic problem. From its base in Ouagadougou in Burkino Faso, west Africa, it has cut the prevalence of infection in the countries in which the disease is most endemic from 95% in 1974 to less than 5% today.

Why has this programme succeeded when practically every other programme in Africa has failed? Its director, Dr Ebrahim Samba, who will take over as regional director for Africa this year, attributes much of the programme's success to its origins. The programme was set up in response to a direct request from the people and governments of seven countries in west Africa. Severe drought was causing famine, while the countries' fertile river beds had been abandoned because of black fly infestation. The World Bank gave the money and WHO the medical expertise, and the United Nations Development Programme and the Food and Agriculture Organisation acted as cosponsors. "The programme is unique because it belongs to the countries in west Africa," said Dr Samba.

Aerial pesticide spraying of the blackfly's breeding grounds has allowed resettlement of 25 million hectares of land, and at a meeting in Paris in April the agriculture and finance ministers of the 11 countries met with donors to decide how this liberated land should be used effectively.

Other ingredients for success, says Dr Samba, have been realistic strategies and good staff and management. "We work from 7 to 12 and from 3 to 6; everyone is on board at five minutes to seven, and nobody touches the money. We have handled over $400m and every cent is accounted for," he said. "This maintains donor confidence."

Progress was greatly enhanced by the introduction in 1988 of the chemotherapeutic drug ivermectin, which is now supplied free of charge by Merck and Co. The programme initially targeted people at severe risk of blindness, then those at lesser risk, and finally those infected but at only minimal risk of blindness. In 1993, over two million people were treated with the drug.

The programme's interventionist approach represents a major departure for WHO. It has its own fleet of helicopters, which have treated over 50 000 km of watercourses, and teams of health workers to find and treat cases. Dr Samba is now working to devolve the programme's case finding and control activities back to the countries themselves by training national health workers to integrate treatment and prevention into their local public health systems. Vector control will continue until 2000.

Dr Samba says that many of WHO's disease control programmes would be more effective and cheaper if they were run from within endemic regions. Dr Hiroshi Nakajima, WHO's director general, disputes this. Programmes dealing with global diseases such as AIDS need to be run, he says, from WHO's centre, where effective lobbying can be done for international action. But others in WHO, including Dr Hussein Gezairy, regional director for the Eastern Mediterranean, believe that resistance comes largely from staff unwilling to leave Geneva.

independent validation of products as a vital role for WHO. But the emphasis still seems to be on finding a single answer, a magic bullet, whether it be the transgenic mosquito or the malaria vaccine. WHO responds to this criticism by pointing to the current efforts to integrate the work of separate special programmes like the tropical diseases research programme and the sick child initiative (box) and to shift the emphasis towards implementation in the field. Promising though these changes are, they remain isolated developments within the organisation as a whole.

Sri Lanka now has over 25 000 cases of malaria a year. As was recognised when the eradication programme was launched, failure would carry grave consequences—a non-immune population exposed to fatal outbreaks with no tools to fight the disease. The message of the malaria debacle, says Dr Spielman, is that, even with dramatically effective tools, there is a need to act with restraint. "We need to identify attainable, worthwhile objectives and then try to act small, to make incremental advances."

"Eradicationitis"

Despite this harsh lesson, "eradicationitis" remains highly prevalent within WHO. The organisation's eagerness to follow on from its success with smallpox is evident in other programmes. According to Dr Diana Lockwood, specialist in leprosy at the Hospital for Tropical Diseases in London, this has led WHO to overplay its success in controlling leprosy, with serious consequences for the funding of control and eradication programmes. "WHO has been very successful in implementing effective antibacterial treatment for leprosy, but it is naive to think that we can eradicate the disease," she said. She believes that WHO's approach to leprosy is too short term and places too much emphasis on drug treatment. "Multiple drug therapy alone is not enough," she said. "Preventing nerve damage and rehabilitating patients is just as important. WHO is doing very little in this area."

Since the early 1980s, when WHO launched its programme to eradicate leprosy by 2000, the number of active cases has fallen from 7m to 3·1m. These figures suggest that WHO is well on the way to achieving its target. But by the WHO definition, patients who have completed a two year course of treatment no longer suffer from leprosy, a definition that takes no account of long term disability and recurrence. Other agencies dealing with leprosy say that WHO's optimistic reports are making it difficult to interest donors in funding leprosy programmes. "The WHO's announcements that the number of cases is falling have taken the pressure off governments and

ANENDEN/WHO PHOTO

Rehabilitating patients with leprosy is just as important as using multiple drug therapy to eradicate the disease

WHO PHOTO

The certificate is proof of success—having eradicated smallpox worldwide, WHO is keen to add other diseases to its books

donors," said Terry Vasey of Lepra, the London based leprosy charity.

The International Federation of Leprosy Associations estimates that 6·5 million people are currently affected by leprosy worldwide and that, despite multidrug treatment, there has been no sign of a decline in the number of new cases. A declaration by members of the federation in July last year emphasised that achieving WHO's current target "does not mean the end of leprosy or of work on behalf of all those people who are and will be affected by the disease."

Making things look good

The pressure to eradicate major tropical diseases by the end of the century has brought with it additional pressures to make the data look good. Aid workers say that they recognise a degree of mutual self deception when gathering data from local health workers. One doctor working for a British based aid agency told me that workers in Ethiopia admitted to falsifying the data on immunisation coverage "because Unicef gave them so much money, they didn't want to disappoint them."

Shifting goal posts is another sign of the millenium approaching, say aid workers. The leprosy programme has changed its target from eradication to elimination of the disease as a public health problem, meaning fewer than one case in 100 000 population. Dr Ebrahim Samba, outgoing director of the onchocerciasis control programme, defends this approach on the grounds that it is not cost effective to pursue a disease to eradication when other priorities need resources. He considers the onchocerciasis programme to have achieved its target now that the prevalence of infection in West Africa is less than 5% (see box). Some commentators remain concerned, however, that closing the programme at this stage carries the risk of recurrence.[6]

Top down interventions

The most dangerous pitfall of eradicationitis, however, remains the distortion of emphasis, from gradual horizontal integration to top down vertical intervention. This is a criticism levied at the joint WHO and Unicef initiative to eradicate polio by the end of the century. Dr Ciro de Quadros, director of the polio eradication programme in the Americas has, say aid workers, achieved astonishing results through his singleminded and single disease oriented approach, but they warn that such a strategy would be highly inappropriate in Africa, where it would be a bad use of resources to invest heavily in the top down eradication of a single disease without developing health care infrastructure in the process.

The vertical approach of most of the special programmes not only undermines WHO's attempts to integrate its initiatives within countries but has also affected the way recipient countries organise their health services. A recent study of health policy and organisation in Ghana concludes that, although the technical concerns of the special programmes have changed—from smallpox, malaria, and yaws before independence to immunisation, Guinea worm, and AIDS today—their organisational structures have remained largely unchanged, and their vertical approach has resulted in separate divisions of the ministry, each controlling its own cadres of staff and concerned with its own area of intervention.[7]

Ironically, having been the beneficiaries of donors' discontent over WHO's regional and country based activities, the special programmes are now themselves being hit. Short of resigning from the organisation, the main way for donors to press home their concerns about WHO's lack of effectiveness is to cut their extrabudgetary contributions. Earlier this month Sweden did just that. One of WHO's most trenchant supporters and the second biggest overall contributor of extrabudgetary funds after America, Sweden announced that it was pulling out half of its funding for the special programmes. Other Nordic countries are considering similar action.

Conclusion

WHO is caught in a cycle of decline, with donors expressing their lack of faith in its central management by placing funds outside the management's control. This has prevented WHO from coordinating its activities in line with centrally agreed priorities and has undermined attempts to develop integrated responses to countries' long term needs. The tendency to give money in extrabudgetary donations was a message to WHO's leaders, says Dr Jonathan Mann. "It was telling WHO that donors wanted more accountability and transparency. They wanted more aggressive, concrete, solid work on important problems. Somehow WHO needs to achieve the same power of response as these programmes achieve but through the mechanisms of the whole organisation." Unless WHO now responds to this message, its hopes of achieving sustainable changes at country level are slim.

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Correction

Controversies in Management: Eradication of *Helicobacter pylori* should be pivotal in managing peptic ulceration. *Helicobacter pylori* is not the causative agent

An editorial error occurred in this article by C O Record (10 December, pp 1571-2). In the first sentence of the third paragraph the percentage of people with bleeding duodenal ulcer who are colonised with *H pylori* should be 71% and not 17%.